REMARKS

In the Office Action dated April 14, 2003, claims 1-6 were rejected under 35 U.S.C. §103(a) as being unpatentable over White in view of Kienzle, III et al. The Examiner stated the White reference discloses a method for preparing an anatomical implant which includes the steps of intra-operatively generating a three-dimensional dataset and intra-operatively preparing the implant from the three-dimensional dataset. The Examiner stated the White reference does not disclose the use of a C-arm, as set forth in independent claims 1 and 6, but the Examiner relied on the Kienzle, III et al reference as disclosing a movable C-arm x-ray apparatus. The Examiner stated it would have been obvious to a person of ordinary skill in the art to modify the apparatus disclosed in the White reference in accordance with the teachings of the Kienzle, III et al reference, because a person of ordinary skill in the art would have been motivated to do so because C-arms are frequently utilized in the art, especially for computed tomography scans as suggested by Kienzle III, et al. The Examiner stated a CT scan "is the process of using digital processing to generate a three-dimensional image of the internal of an object of two-dimensional x-ray images."

This rejection is respectfully traversed for the following reasons. First, Applicants do not agree that the White reference teaches intra-operatively obtaining a 3D dataset of a region of a subject in which an implant is to be implanted, nor does the White reference teach intra-operatively preparing an implant for implantation into the subject. The term "intra-operatively" as used in the claims, and as described in the present specification, was intended to mean that both of these steps take place during an actual medical interventional, i.e. surgical, procedure for implanting the

implant. By contrast, the White reference teaches conducting the scan prior to the surgical operation, and producing the implant prior to the surgical operation. This is one reason why the White reference uses relatively bulky and large CT systems or MRI systems for generating the three-dimensional dataset. Imaging systems of that type cannot be used in an operating room environment. Moreover, in both of those types of imaging systems, the patient proceeds through an opening (actually a tunnel in the case of an MRI system) which would not allow access to the patient by a physician for conducting an interventional medical procedure.

Despite the intended meaning of the term "intra-operatively" in the claims as originally filed, as defined in the present specification, Applicants recognize that this term may not necessarily, in its broadest definition, define that the steps take place during a medical interventional procedure. Each of independent claims 1 and 4, therefore, has been amended to supply this specific limitation. The White reference, therefore, clearly does not disclose or suggest method steps or apparatus components which can be used to obtain a three-dimensional dataset during a medical interventional procedure, nor to produce a medical implant from the 3D image dataset during the medical interventional procedure.

The Examiner's reliance on the Kienzle, III et al reference actually is evidence supporting the non-obviousness of claims 1-6, rather than a basis for justifying a rejection of those claims under 35 U.S.C. §103(a). The Kienzle, III et al is physically incapable of producing a three-dimensional dataset of a subject, and in fact is only capable of producing, and is only intended to produce, a two-dimensional image. This is explicitly stated at numerous locations in the Kienzle, III et al reference such as in the third sentence of the abstract. Although the device disclosed in the Kienzle,

III et al reference is referred to as "computer assisted" it is not a computed tomography apparatus, but is instead a fluoroscopic apparatus.

As is well known to those of ordinary skill in the art, for producing a 3D dataset, all known algorithms require that the x-ray source and the detector be able to be rotated around the subject (i.e. around an axis proceeding through the subject) through an angular range of at least approximately 190° (i.e. 180° plus the fan angle of the x-ray beam). The C-arm apparatus disclosed and claimed in the present application is able to do this because the x-ray source and the x-ray detector are mounted at the interior circumference of the C-arm, thereby permitting the outer circumference of the C-arm to be moved through the arcuate C-arm holder over the requisite angular range of at least approximately 190°.

Despite the fact that the Kienzle III et al reference is a fluoroscopy device, and is not used to produce a three-dimensional image, it would not even be considered by a person of ordinary skill in the art as appropriate for being operable in an attempt to produce a 3D image, because the radiation source and the radiation detector have portions located at the outer circumference of the C-arm, thereby precluding the C-arm from even being rotated through 180°.

Nevertheless, Applicants acknowledge that C-arm x-ray systems have been used in, and are known to be suitable for use in, an operating room environment in order to generate a 3D dataset to produce an image for monitoring the progress of a medical interventional procedure. The Kienzle, III et al reference, however, is not an example of such a device, and could not be modified for use for such a purpose.

Nevertheless, despite the known use of C-arm x-ray devices for producing a 3D dataset to monitor the progress of a medical intervention, it has heretofore not

been known to use such a device to inter-operatively generate a 3D dataset during a medical interventional procedure in order to produce a medical implant from that dataset during the same medical interventional procedure, as disclosed and claimed in the present application. The fact that the Examiner has cited a C-arm device which is incapable of being used in the inventive method or apparatus demonstrates that it is not simply a matter of substituting any sort of C-arm device for the bulky scanner systems disclosed in the White reference. First, a person of ordinary skill in the art must have the insight to realize that it is even possible to produce a medical implant "on the fly" (i.e. during an actual medical procedure for implanting the implant), and then such a person must have enough additional insight to employ an appropriate type of 3D imaging device suited for that particular purpose. It is clear that neither the White reference nor the Kienzle, III et al reference provides any teachings whatsoever which would assist a person of ordinary skill in the art in selecting the "right" type of 3D dataset imaging device, and in fact if a person of ordinary skill in the art followed the teachings of White or Kienzle, III et al, the apparatus and method of the present invention could not even be achieved. This is because the White reference does not allow intra-operative imaging, and does not teach intra-operative generation of the implant, and the Kienzle, III et al reference is incapable of three-dimensional imaging, intra-operatively or otherwise.

Applicants believe the present amendment to independent claims 1 and 4 are sufficient to distinguish those claims over the teachings of the references of record, as well as original claims 2 and 3 depending from claim 1 and original claims 5 and 6 depending from claim 4. Moreover, new claims 7 and 8 depending from method claim 1 and 9 and 10 depending from apparatus claim 4 have been added, which set

forth the aforementioned method steps and structure for being able to accomplish the generation of a 3D dataset. No such structure or method steps is disclosed or suggested in any of the references of record.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

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